

REMARKS**Status of the Claims**

Claims 2, 6, and 10 have been canceled without prejudice. Claims 30-66 have been added, support for which can be found, for example, on page 3, lines 1-3, page 5, lines 2-7, page 8, lines 18-28, and page 9, lines 29-32, of the specification. Claims 1, 3-5, 7-9, 11-22 and 29-66 are pending and at issue.

Rejections Under 35 U.S.C. §102

Claims 1-22 and 29 have been rejected under 35 U.S.C. §102(b) as anticipated by International Publication No. WO 96/30036 ("the '036 Publication"). The Examiner contends that disodium salts are inherently formed *in situ* when the compounds are treated with sodium hydroxide.

Applicants respectfully traverse this rejection and request reconsideration.

According to the July 28, 2005 Office Action, this rejection "still stands" from the June 23, 2004 Office Action. However, the June 23, 2004 Office Action indicated that claims 2, 6, and 10 (which are directed to disodium salts of *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid) would be allowable if rewritten in independent form. Now these claims are said to be rejected over the '036 Publication, without any basis for the rejection being provided. Notwithstanding this omission, applicants have addressed the rejection of claims 2, 6, and 10 below, which have been rewritten in independent form as claims 59-61.

The '036 Publication does not disclose the delivery agent *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid, as recited in and 29 and 59-61 (as well as claims 30-58 and 62-66). Nor does the '036 Publication disclose a method of administering salmon calcitonin with the disodium salt of *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid as recited in claim 29-58. Therefore, these claims are not anticipated by the '036 Publication.

Furthermore, a *prima facie* case of anticipation has not been established for the remaining claims. “When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.” 37 C.F.R. §1.104(c)(2) (emphasis added). *See also* M.P.E.P. §2112(IV) (“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art”); *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The June 23, 2004 and July 28, 2005 Office Actions, however, do not refer to any specific passages or examples in the ‘036 Publication. Therefore, a proper basis has not been provided for this rejection.

Additionally, the examples in the ‘036 Publication do not necessarily produce a disodium salt of a delivery agent compound encompassed by the generic formula in pending claim 1. For instance, Example 1 does not specify the amount of sodium hydroxide added to the solution. “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” *See* M.P.E.P. §2112(IV) (*citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)).

For the foregoing reasons, the ‘036 Publication does not anticipate claims 1, 3-5, 7-9, 11-22 and 29. Accordingly applicants request withdrawal of this rejection.

In view of the above remarks, applicant believes the pending application is in condition for allowance.

Dated: December 28, 2005

Respectfully submitted,

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